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10/553,812	10/02/2006	Carina P. Tan	21198P	8658

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MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	PAPER NUMBER
1646	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,812	TAN ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☒ Claim(s) *1 and 8-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/05; 1/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The preliminary amendment of 10/18/05 has been entered in full. Claims 5, 11, 12 and 13 are amended.

Claims 1-14 are under consideration in the instant application.

Specification

The disclosure is objected to because, in the Brief Description of the Drawings (pg 6), the description of Figure 3 does not refer to Fig. 3A, 3B, 3C or 3D, and the description of Figure 4 does not refer to Fig. 4A or 4B. See 37 CFR § 1.74, which states "When there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures and to the different parts by use of reference letters or numerals (preferably the latter)" and MPEP 601.01(g) which states "if the drawings show Figures 1A, 1B, and 1C and the brief description of the drawings refers only to Figure 1, this is an error in the specification which must be corrected."

Appropriate correction is required.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The Declaration submitted on 10/2/06 lists PCT/US2004/011473 under "Prior Foreign Application Number(s)" (pg 1), but fails to mark either "YES" or "NO" in the last column (titled "Priority Claimed?"). It is presumed that "YES" should be marked as Applicants amended the first line of the specification on 10/18/05 to indicate that the instant application is a 371 of said PCT.

Claim Objections

Claims 1 and 8-14 are objected to because of the following informalities:

(1) The term "rhesus monkey bombesin receptor subtype-3" is abbreviated inconsistently in claims 1 and 8-14. In claims 1 and 8-10, it is partially abbreviated as "rhesus monkey BRS-3". In claim 11, it is fully written out "rhesus monkey bombesin receptor subtype-3" and given the partial abbreviation "BRS-3". However, in claim 12, it is written "rhesus monkey BRS-3 (rhBRS-3)". Claim 13 uses "rhBRS-3" and "rhesus monkey BRS-3 protein" separately. Claim 14 depends ultimately from claim 1 but uses "rhBRS-3" instead of "BRS-3".

For clarity, it is suggested that the first time the term is used (in claim 1) that it is fully written out as "rhesus monkey bombesin receptor subtype-3 (rhBRS-3)" and then in all subsequent usages (in claims 8-14) simply abbreviated as rhBRS-3.

(2) Claim 13 recites "(a) combining a test substance in the presence and absence of the rhesus monkey BRS-3 of claim 10..." The word "combining" indicates the joining of two parts. However, the claim does not indicate what the test substance will be "combined" with in the absence of rhesus monkey BRS-3.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph, enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 12 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) an isolated host cell comprising the vector of claim 6; and (2) a method of screening using said isolated host cell, does not reasonably provide enablement for (3) a host cell comprising the vector of claim 6 or (4) a method of screening using said host cell. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are directed to a broad genus of host cells comprising an expression vector that, in turn, comprises the claimed DNA, and corresponding methods of screening using said host cells. The specification contemplates two subgenera in which such host cells can be made and used. Specifically, the specification contemplates making and using the host cells in culture and in multicellular, transgenic organisms.

(1) The specification contemplates making and using isolated host cells in culture to produce the encoded protein recombinantly. Such is enabled, since the specification and prior art provide specific guidance on how to make and use host cells for this purpose. Undue experimentation would not have been required of the skilled artisan to make and use the claimed host cells in this context.

(2) The specification also "the present invention relates further to transgenic animals, either an invertebrate (e.g., C. elegans) or vertebrate (e.g., mouse), for which the gene encoding rhBRS-3 has been introduced into the germline of the animal (¶ 83 of the published application). However, there are no methods or working examples disclosed in the instant application whereby a multicellular animal with the incorporated claimed gene is demonstrated to express the encoded peptide. There are also no methods or working examples in the specification indicating that a multicellular animal has the claimed gene "knocked out". The unpredictability of the art is *very high* with regards to making transgenic animals. For example, Wang et al. (Nuc. Acids Res. 27: 4609-4618, 1999; pg 4617) surveyed gene expression in transgenic animals and found in each experimental animal with a single "knock-in" gene, multiple changes in genes

and protein products, often many of which were unrelated to the original gene. Likewise, Kaufman et al (Blood 94: 3178-3184, 1999) found transgene expression levels in their transfected animals varied from "full" (9 %) to "intermediate" to "none" due to factors such as "vector poisoning" and spontaneous structural rearrangements (pg 3180, col 1, 2nd full paragraph; pg 3182-3183).

Due to the large quantity of experimentation necessary to generate a transgenic animal expressing the disclosed protein, the lack of direction/guidance presented in the specification regarding how to introduce the claimed nucleic acid in the cell of an organism to be able produce the encoded protein, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art that establishes the unpredictability of making transgenic animals, and the breadth of the claims which fail to recite any cell type limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Please note that this rejection could be overcome by amending the claims to recite, for example, "An isolated host cell…" because such an amendment would clarify that the claims are directed only to host cells that are to be made and used in culture as described in context (1) above.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 11 is directed to a "method for identifying compounds that modulate rhesus monkey bombesin receptor subtype-3 (BRS-3) expression, comprising contacting a test compound with the BRS-3 protein of claim 10 and determining whether the test compound interacts with rhesus monkey bombesin receptor subtype-3". The rhBRS-3 protein of claim 10 is "[a]n isolated and purified protein". Thus, claim 11 is limited to methods of screening comprising contacting test compounds with an isolated and purified rhBRS-3 protein and determining whether interaction (i.e. binding) between these two components occurs. However, a method comprising these steps does not

enable the skilled artisan to achieve the preamble recited in the claim, i.e. identification of a compound that modulates BRS-3 expression. The expression level of a protein is a characteristic of the protein when it is expressed by a cell. Screening methods that identify binding partners with an isolated and purified protein do not provide any information as to whether the binding partner will also alter the expression level of the protein in a cell. Many partners may bind to a protein expressed in a cell without altering the expression level. The specification does not teach that binding to rhBRS-3 is correlated with modulation of expression, nor provide any working examples indicating that binding partners also regulate the expression level of the protein. Due to the large quantity of experimentation necessary to determine if there is a correlation between binding to an isolated rhBRS-3 protein and the ability to modulate expression of said protein in a cell, the lack of direction/guidance presented in the specification regarding same, lack of working examples and the teachings of the prior art and the complex nature of the invention, undue experimentation would be required of the skilled artisan to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lane et al, U.S. Patent 6,143,521, published 11/7/2000 (cited on the 10/18/05 IDS).

Claim 1 is directed to an isolated nucleic acid molecule comprising a sequence of nucleotides that encodes a rhesus monkey BRS-3 protein as set forth in SEQ ID NO: 1. Nucleic and amino acid sequences are frequently claimed using open language and "a" or "the" to refer to sequences identified by SEQ ID NOs, for example (1) "a nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1" or (2) "a nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1". However, these two phrases result in claims of very different scope, because the first encompasses nucleic acids that comprise the

full-length sequence of SEQ ID NO: 1 or any fragment of SEQ ID NO: 1. The second phrasing encompasses only nucleic acids that comprise the full length of SEQ ID NO: 1. Therefore, the phrase used in claim 1 ("a sequence of nucleotides that encodes a rhesus monkey BRS-3 protein as set forth in SEQ ID NO: 2") encompasses nucleic acid molecules that encode any shorter amino acid sequence found within SEQ ID NO: 2 (i.e., sequences comprising any fragment of SEQ ID NO: 2). The '521 patent teaches a protein sequence of SEQ ID NO: 2 of 399 amino acids that is 96.5% identical to instant SEQ ID NO: 2 and contains numerous shorter sequences that are 100% identical to subsequences in instant SEQ ID NO: 2, as shown in the following alignment:

```
  Query Match             96.5%;  Score 1975.5;  DB 2;  Length 399;
  Best Local Similarity   96.7%;  Pred. No. 5.3e-170;
  Matches  385;  Conservative    7;  Mismatches    5;  Indels    1;  Gaps    1;

Qy          1 MAQRQPHSPNQTLISITNDTE-SSSVVSNDNTNKGRSGDNSPGIEALCAIYITTAVIISV 59
              |||||||||||||||||||| |||||||||||| |||||||||||||||||||||||||||
Db          1 MAQRQPHSPNQTLISITNDTESSSSVVSNDNTNKGWSGDNSPGIEALCAIYITTAVIISV 60

Qy         60 GILGNAILIKVFFKTESMQTVPNIFITSLAFGDLLLLLTCVPVDATHYLAEGWLFGRIGC 119
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 GILGNAILIKVFFKTESMQTVPNIFITSLAFGDLLLLLTCVPVDATHYLAEGWLFGRIGC 120

Qy        120 KVLSFIRLTSVGVSVFTLTILSADRYKAVVKPLERQPSNAILKTCIKAGCVWIVSMIFAL 179
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 KVLSFIRLTSVGVSVFTLAILSADRYKAVVKPLERQPSNAILKTCVKAGCVWIVSMIFAL 180

Qy        180 PEAIFSNVYSFRDPNKNVTFESCTSYPVSKELLQEIHSLLCFLVFYIIPLSIISVYTSLI 239
              |||||||||:|||||||:|||||||||||||||||||||||||||||||||||||||||||
Db        181 PEAIFSNVYTFRDPNSNNTFESCTSYPVSKELLQEIHSLLCFLVFYIIPLSIISVYTSLI 240

Qy        240 ARTLYKSTLNIPTEEQGHARKQIESRKRIARTVLVLVALFALCWLPNHLLYLYHSFTSQT 299
              ||||||||||||| |||||||||||||||||||||||||||||||||||||||||||||||
Db        241 ARTLYKSTLNIPTEEQSHARKQIESRKRIARTVLVLVALFALCWLPNHLLYLYHSFTSQT 300

Qy        300 YVDPSAHHFIFTIFSRVLAFSNSCVNPFALYLSKTFQKHFKAQLFCCKAEQPEPPVADT 359
              |||||||||||||||||||||||||||||||||:|||||||||||||:||||||||||||
Db        301 YVDPSAHHFIFTIFSRVLAFSNSCVNPFALYLSKSFQKHFKAQLFCCKAERPEPPVADT 360

Qy        360 SLTTLAVHGWVPGTGNNQHSEISVTSFPGCSVKQAEDR 397
              ||||||| |||||::|||||||||| ||||||||||
Db        361 SLTTLAVHGTVPGTGSIQHSEISVTSFTGCSVKQAEDR 398
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The '521 patent further teaches a nucleic acid of SEQ ID NO: 1 that encodes SEQ ID NO: 2. This nucleic acid sequence is encompassed by claim 1, and therefore the '521 patent anticipates instant claim 1.

The '521 patent further teaches that SEQ ID NO: 1 is a cDNA sequence (col 4, line 54), which anticipates claims 2 and 4.

The '521 patent further teaches mRNA produced from DNAs of the invention (col 6, line 55), which anticipates claim 3.

Claim 5 is anticipated by SEQ ID NO: 1 of the '521 patent for similar reasons as claim 1; i.e., claim 5 encompass isolated nucleic molecules that comprise "a sequence of nucleotides as set forth in SEQ ID NO: 1". SEQ ID NO: 1 of the '521 patent comprises numerous subsequences that are 100% identical to subsequences shown in instant SEQ ID NO: 1, as shown in the following alignment:

```
  Query Match             95.2%;  Score 1139.2;  DB 3;  Length 1205;
  Best Local Similarity   97.4%;  Pred. No. 0;
  Matches 1169;  Conservative    0;  Mismatches   28;  Indels    3;  Gaps    1;

Qy          1 ATGGCTCAAAGGCAGCCTCACTCACCTAATCAGACTTTAATTTCAATCACAAATGACACA 60
              |||||||||||||||||||||||||||||||||||||| |||||||||||||||||||||
Db          3 ATGGCTCAAAGGCAGCCTCACTCACCTAATCAGACTCTAATTTCAATCACAAATGACACA 62

Qy         61 GA---ATCAAGCTCTGTGGTTTCTAACGATAACACAAATAAAGGACGGAGCGGGGACAAC 117
              ||   |||||||||||||||||||||||| ||||| |||||||| ||||||||||||||
Db         63 GAATCATCAAGCTCTGTGGTTTCTAACGACAACACGAATAAAGGATGGAGCGGGGACAAC 122

Qy        118 TCTCCAGGAATAGAAGCATTGTGTGCCATCTATATTACTTATGCTGTGATCATTTCAGTG 177
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        123 TCTCCAGGAATAGAAGCATTGTGTGCCATCTATATTACTTATGCTGTGATCATTTCAGTG 182

Qy        178 GGCATCCTTGGAAATGCTATTCTCATCAAAGTCTTTTTCAAGACCAAATCCATGCAAACA 237
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        183 GGCATCCTTGGAAATGCTATTCTCATCAAAGTCTTTTTCAAGACCAAATCCATGCAAACA 242

Qy        238 GTTCCAAATATTTTCATCACCAGCCTGGCTTTTGGAGATCTTTTACTTCTGCTAACTTGT 297
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        243 GTTCCAAATATTTTCATCACCAGCCTGGCTTTTGGAGATCTTTTACTTCTGCTAACTTGT 302

Qy        298 GTGCCAGTGGATGCAACCCACTACCTTGCAGAAGGATGGCTGTTCGGAAGAATTGGTTGT 357
              ||||||||||||||| |||||||||||||||||||||||||||||||||||||||||||
Db        303 GTGCCAGTGGATGCAACTCACTACCTTGCAGAAGGATGGCTGTTCGGAAGAATTGGTTGT 362

Qy        358 AAGGTGCTCTCTTTCATCCGGCTCACTTCTGTTGGTGTGTCAGTGTTCACGTTAACAATT 417
              |||||||||||||||||||||||||||||||||||||||||||||| ||| ||||||
Db        363 AAGGTGCTCTCTTTCATCCGGCTCACTTCTGTTGGTGTGTCAGTGTTCACATTAGCAATT 422

Qy        418 CTCAGCGCTGACAGATACAAGGCAGTTGTGAAGCCACTTGAGCGACAGCCCTCCAATGCC 477
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        423 CTCAGCGCTGACAGATACAAGGCAGTTGTGAAGCCACTTGAGCGACAGCCCTCCAATGCC 482

Qy        478 ATCCTGAAGACTTGTATAAAAGCTGGCTGCGTCTGGATCGTGTCTATGATATTTGCTCTA 537
              ||||||||||||||| |||||||||||||||||||||||||||||||||||||||||||
Db        483 ATCCTGAAGACTTGTGTAAAAGCTGGCTGCGTCTGGATCGTGTCTATGATATTTGCTCTA 542

Qy        538 CCTGAGGCTATATTTTCAAATGTATATTCTTTTCGAGATCCCAACAAAAATGTGACATTT 597
              |||||||||||||||||||||||||  |||||||||||||| |||||| ||||||||
Db        543 CCTGAGGCTATATTTTCAAATGTATACACTTTTCGAGATCCCAATAAAAATATGACATTT 602

Qy        598 GAATCGTGTACCTCTTATCCTGTCTCTAAGAAGCTCTTGCAAGAAATACATTCTCTGCTG 657
              ||||| |||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        603 GAATCATGTACCTCTTATCCTGTCTCTAAGAAGCTCTTGCAAGAAATACATTCTCTGCTG 662
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Qy        658 TGCTTCTTAGTGTTCTACATTATTCCACTCTCTATTATCTCTGTCTATTATTCTTTGATT 717
              ||||||||||||||||||||||||||||||||||||||||||||||||||| ||||| ||||||
Db        663 TGCTTCTTAGTGTTCTACATTATTCCACTCTCTATTATCTCTGTCTACTATTCCTTGATT 722

Qy        718 GCTAGGACCCTTTATAAAAGCACCCTGAACATACCTACTGAGGAACAAGGCCATGCCCGT 777
              |||||||||||||| ||||||||||||||||||||||||||||||||||| ||||||||||
Db        723 GCTAGGACCCTTTACAAAAGCACCCTGAACATACCTACTGAGGAACAAGGCCATGCCCGT 782

Qy        778 AAGCAGATTGAATCCCGGAAGAGAATTGCCAGAACGGTATTGGTGTTGGTGGCTCTGTTT 837
              ||||||||||||||||| ||||||||||||||||||||||||||||||||||||||||||||
Db        783 AAGCAGATTGAATCCCGAAAGAGAATTGCCAGAACGGTATTGGTGTTGGTGGCTCTGTTT 842

Qy        838 GCCCTCTGCTGGTTGCCAAATCACCTCCTGTACCTCTACCATTCATTCACTTCTCAAACC 897
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        843 GCCCTCTGCTGGTTGCCAAATCACCTCCTGTACCTCTACCATTCATTCACTTCTCAAACC 902

Qy        898 TATGTAGACCCCTCTGCCATGCATTTCATTTTCACCATTTTCTCTCGGGTTCTGGCTTTC 957
              |||||||||||||||||||||||||||||||||||||||||||||||||| ||||||||
Db        903 TATGTAGACCCCTCTGCCATGCATTTCATTTTCACCATTTTCTCTCGGGTTTTGGCTTTC 962

Qy        958 AGCAATTCTTGCGTAAACCCCTTTGCTCTCTACTGGCTGAGCAAAACCTTCCAGAAGCAT 1017
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        963 AGCAATTCTTGCGTAAACCCCTTTGCTCTCTACTGGCTGAGCAAAAGCTTCCAGAAGCAT 1022

Qy       1018 TTTAAAGCTCAGTTGTTCTGTTGCAAGGCAGAGCAGCCTGAGCCTCCTGTTGCTGACACC 1077
              |||||||||||||||||||||||||||||| |||| ||||||||||||||||||||||||
Db       1023 TTTAAAGCTCAGTTGTTCTGTTGCAAGGCGGAGCGGCCTGAGCCTCCTGTTGCTGACACC 1082

Qy       1078 TCTCTTACCACCCTGGCTGTGATGGGAAGGGTCCCGGGCACTGGGAACATGCAGATGTCT 1137
              |||||||||||||||||||||||||||||||||||||||||||||||| ||| ||||||||||
Db       1083 TCTCTTACCACCCTGGCTGTGATGGGAACGGTCCCGGGCACTGGGAGCATACAGATGTCT 1142

Qy       1138 GAAATTAGTGTGACCTCGTTCCCTGGGTGTAGTGTGAAGCAGGCAGAGGATAGAGTCTAG 1197
              |||||||||||||||||| ||||||||||||||||||||||||||||||||||| ||||||
Db       1143 GAAATTAGTGTGACCTCGTTCACTGGGTGTAGTGTGAAGCAGGCAGAGGACAGATTCTAG 1202
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The '521 patent further teaches expression vectors, host cells and processes for expressing the protein comprising culturing a host cell comprising a vector comprising nucleic acids of the invention (see col 6, starting at line 45). These teachings anticipate instant claims 6, 7 and 9.

The '521 patent further teaches membranes containing the polypeptide of the invention (see col 11, line 1), which anticipates claim 8.

The amino acid sequence of SEQ ID NO: 2 taught by the '521 patent anticipates instant claim 10 for reasons analogous to claim 1 above; i.e., instant claim 10 encompasses any polypeptide that comprises "a sequence of amino acids as set forth in SEQ ID NO: 2".

The recitation of "for identifying compounds that modulate rhesus monkey bombesin receptor subtype-3 (BRS-3) expression" in the preamble of claim 11 is interpreted as an intended use and bears no accorded patentable weight to distinguish the claimed process over one from the prior art. As such, claim 11 encompasses a

method comprising "contacting a test compound with the BRS-3 protein of claim 10, and determining whether the test compound interacts with rhesus monkey bombesin receptor subtype-3". The '521 patent further teaches method of screening candidate compounds by measuring binding of the compound to the polypeptide of the invention (col 10, line 66-67), which anticipates claim 11.

The '521 patent teaches that "HEK293 or CHO cells transfected with the vector alone serve as negative controls" (Example 1) for use in ligand binding screening assays with cells expressing polypeptides of the invention (Example 2-3). These teachings anticipate instant claim 12.

The recitation of "identifying a substance which modulates rhBRS-3 receptor activity" in the preamble of claim 13 is interpreted as an intended use and bears no accorded patentable weight to distinguish the claimed process over one from the prior art. As such, claim 13 encompasses a method comprising "(a) combining a test substance in the presence and absence of the rhesus monkey BRS-3 protein of claim 10; and (b) measuring and comparing the effect of the test substance in the presence and absence of the rhBRS-3 protein". The "effect" of the test substance broadly encompasses "binding" to the protein. Therefore, the teachings of the '521 patent at column 10, lines 66-67 described above also anticipate claim 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lane et al, U.S. Patent 6,143,521, published 11/7/2000 (cited on the 10/18/05 IDS).

The recitation of "determining whether a substance is a potential agonist or antagonist of rhBRS-3" in the preamble of claim 14 is interpreted as an intended use and bears no accorded patentable weight to distinguish the claimed process over one

from the prior art. Furthermore, the concluding statement, "where if the amount of binding of the labeled ligand is less in the presence of the substance than in the absence of the substance, then the substance is potential agonist or antagonist of rhBRS-3" is merely an inherent quality of any substance that binds to the rhBRS-3 polypeptide with greater affinity than the labeled ligand. As such, claim 14 encompasses any method comprising steps (a)-(d) as recited in the claim.

As described above, the '521 patent teaches host cells comprising an expression vector encoding a nucleic acid of claim 1, and expression of the protein using said host cells. The '521 patent further teaches screening using "competition with a labeled competitor". The '521 patent further teaches antibodies to the polypeptide of the invention. As antibodies bind to the polypeptide, they are encompassed by the term "ligand" used in claim 14. Lane does not specifically teach using a "labeled ligand" as the "labeled competitor".

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use an antibody (which is a species of labeled ligand) taught by Lane as a labeled competitor in a method of competitive screening with a test compound as taught by Lane. The person of ordinary skill in the art would have been motivated to make that modification in order to have a labeled competitor for use in the screening taught by Lane.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Z. C. H./
Examiner, Art Unit 1646

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646